

April 2017

OECD ADVERSE OUTCOME PATHWAY

Project Submission Form

If you require further information please contact the OECD Secretariat
Return completed forms to our generic account (env.tgcontact@oecd.org), and Nathalie
Delrue (Nathalie.delrue@oecd.org)

PROJECT TITLE

Adverse Outcome Pathways Knowledge Base 2.0 (AOP-KB)

SUBMITTED BY (Country / European Commission / Secretariat)

European Commission – DG Joint Research Centre
and
US Environmental Protection Agency

DATE OF SUBMISSION TO THE SECRETARIAT

2017-xx-xx

DETAILS OF LEAD COUNTRY/CONSORTIUM

Country/Organisation:	European Commission	US EPA	OECD
Agency/ministry/Other :	DG Joint Research Centre	US EPA Mid-Continent Ecology Division	Environmental Health and Safety Division
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PROJECT CATEGORY

☐ Development of an AOP - applicable to a chemical category

Select the development tool to be used

☐ AOP-Wiki ☐ Effectopedia

☐ Guidance document related to AOP development including its evaluation

☒ Knowledge management tool for supporting AOP development including its evaluation

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☐ Other, please specify below

If other category, please specify:

PROJECT DESCRIPTION

Please provide sufficient information to facilitate the review of the project submission by the OECD secretariat and the Extended Advisory Group with respect to its suitability to be included in the workplan of the AOP programme.

The Adverse Outcome Pathway-Knowledge Base (AOP-KB) is currently implemented as a federated system consisting of individual modules that serve unique roles within the knowledgebase and a portal that provides access to information from all the individual modules. Currently, two content-containing modules (AOP-Wiki and Effectopedia) have been launched with a third module (Intermediate Effects Database - IEDB) expected in 2018. Release of the IEDB is pending an ongoing review of the OECD Harmonized Template 201, which is the basis for capturing the information for this module. The AOPXplorer module is set to launch in 2017 and is currently available for beta testing. Rather than providing original content, the AOPXplorer is an analysis tool that will provide advanced capabilities for interacting with the data from the AOP-KB and merging this information with data from other sources. The AOPXplorer will, however, provide network views for the content containing modules based on the AOPs contained therein. The e.AOP.Portal represents the public face of the AOP-KB and provides a single OECD managed access point that allows programmatic and end user access to AOP KB distributed across the connected modules. An XML standard has been defined to describe the minimal data exchange format for the AOP-KB modules, and all modules will be adding support for the AOP-XML format by 2018.

Having successfully deployed modules to support the development, evaluation, and quantitative description of AOPs, as well as the assembly of AOP networks, we now propose a full redesign of the AOP-KB to provide a single centralized KB that houses all content: This will consolidate an organically grown situation, will address issues with the adequate selection of the appropriate tool to start an AOP, and will also overcome potential inter-module data synchronisation problems. Existing modules will be retired or converted into third party analysis tools. Because all AOP development needs are being met by the current system, we propose a complete redesign of the system based on the well-established process for developing AOPs and feedback from existing AOP developers on the strengths and weaknesses of the current AOP-KB modules. The current system was designed as the AOP development process was being refined and thus the alignment between the IT system functionality and the final AOP development work flow was, for obvious reasons, not 100%. In addition, many uses of AOP information have now been established, which allows a newly designed system to focus not just on supporting AOP development but also translating the information to support the varied uses identified.

The code base from the existing modules will be used as appropriate for the new system, and design elements from existing modules that are endorsed by AOP developers will drive the design of the new system. No a priori decisions will be made about the final design or implementation, however, until after thorough consideration of user feedback and the new design considerations outlined above. Existing modules will be maintained until the new system is available thereby removing the need to set arbitrary timelines for launch. Instead, the timeline will be established after the requirements gathering has been completed and an implementation plan is in place.

All data from the two content-containing modules will be transferred to the new system along with the revision history for the content. Legacy information that cannot be transferred into the new system will be made available via static web pages that are linked from the new system. An example of this approach is the incorporation of the original AOP-Wiki pages, including history, into the AOP-Wiki 2.0, which provides the full revision history for the content while only transferring the current content into the new system. The newly established AOP-XML schema should make the data transfer simple and error-free because both of the existing modules will support the XML export option by the end of 2017. Starting with the AOP-KB 2.0 release, third party tools will also be able to upload AOP information into the knowledgebase programmatically using the AOP-XML format.

This proposal will replace, once AOP-KB 2.0 will have been successfully implemented and deployed, projects 4.2 and 4.3 on the current AOP development programme workplan, which will be the projects under which any necessary maintenance of AOP Wiki and Effectopedia will be executed.

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Note: For AOP Development projects please indicate the extent of the pathway to be described (i.e. the anchor points), the intermediate events that are likely to be addressed, the state of current development, the degree to which this pathway is already understood and described in the literature, and the expectation on the availability of evidence to support the AOP. Proposers should also indicate if and how the AOP is associated to any regulatory toxicological endpoints (e.g. acute or chronic toxicity, toxicity to reproduction etc.) Please provide references, links or attachments for supplementary information.

PROJECT PLANNING

In this section, please provide an indication of when the project is likely to commence and the expected duration. Please also make reference to any particular milestones or external factors that will influence project planning, and if the project is linked to programmes of particular organisations or consortia.

The project will proceed in three phases:

1. Requirements capturing
2. System specifications
3. System development

Phase 1 has already begun with the development of surveys for existing AOP developers and a review of the previous requirements from the development of the current knowledgebase. This phase will continue with a series of individual interviews with AOP authors on their experience with the existing tools. In addition to AOP developers, an outreach effort to potential users of the AOP information (e.g. members of the Working Party for Hazard Assessment) will be initiated to incorporate design elements to support their needs. Towards the end of phase 1, authors and users will be presented with mockups for the proposed system and possibly some rudimentary prototypes. It is anticipated that this phase would take 6 months to a year to complete depending on the resources available to solicit and consolidate the user feedback.

Phase 2 will proceed in parallel with phase 1, and initial specifications will be driven by early feedback from users of the existing tools focused on the AOP development process. As additional user feedback is received, the system specifications will be revised and used to develop the mockups and early prototypes for the later stages of phase 1. The system specifications will not include any implementation details and early prototypes will not represent a commitment to any specific software platform. Due to the iterative nature between phases 1 and 2, phase 2 should be completed within 1-2 months of the completion of phase 1.

At the completion of phase 2, a vendor will be identified to develop the system, and the vendor will develop an implementation plan based on the system specifications in collaboration with the AOP-KB development team. Timing of phase 3 will be determined once the implementation plan is completed. The development will be via an Agile development process with early prototypes for user feedback. It is also anticipated that the launch of the AOP-KB 2.0 system will occur during rather than after phase 3. Once the minimum requirements needed to replace the current system have been met and tested, the AOP-KB 2.0 will replace existing modules and become the central repository for all AOP information. Additional features that aren't included in the current AOP-KB will be added as they are completed.

The most relevant external factor that will influence the project is financing: While the project will be steered by the consortium (US, EC and OECD) in accordance with the EAGMST, the budget source for the system development by a vendor is currently being explored by the OECD. The project timeline, and other decisions, could be influenced by conditions under which a third party provides budget.

FLOW DIAGRAM

In this section, please provide a flow diagram of the proposed AOP, including the MIE, KEs at the various stages (molecular interaction, cellular response, organ response) and the AO.

